SEP 3 0 2005

K05 2220

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510 (k) Summary of Safety and Effectiveness for iPlan RT FiberTracking

Manufacturer:

Address: BrainLAB AG
Ammerthalstrasse 8
85551 Heimstetten
Germany
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Contact Person: Mr. Per Persson

Summary Date: August 11, 2005

Device Name:

Trade name: iPlan RT FiberTracking

Common/Classification Name: Planning System / Medical charged-particle radiation therapy system

Predicate Device:
iPlan! FiberTracking (K041703).
Intuition Image (K032511).

Device Classification Name: Medical charged-particle radiation therapy system
Regulatory Class: Class II

Indications For Use:

iPlan RT FiberTracking's indications for use is to prepare and present patient and image data based on CT, MR, Angiographic and other imaging sources including

- image preparation
- image localization
- image fusion
- image segmentation
- isocenter handling
- plan review and approval
- fiber tracking

where the result is used for stereotactic radiation treatment planning that is intended for use in stereotactic, conformal, computer planned, LINAC based radiation treatment of cranial, head and neck and extracranial lesions.

Fiber Tracking:

iPlan RT FiberTracking's indication for use is to prepare and present patient and image data based on MRI scanned with diffusion-weighted sequences. These diffusion images are used for the calculation and display of

fiber bundles in a selected region of interest. The created treatment plans of iPlan RT FiberTracking can be used with other iPlan treatment plans and other BrainLAB medical devices such as BrainSCAN, iPlan RT Image, and iPlan RT Dose where this medical device is used for radiotherapy treatment planning.

Device Description:
iPlan RT FiberTracking is developed to enhance the functionality of Intuition Image software with the import and planning of diffusion tensor images (DTI). Additional to the basic functions of Intuition Image (viewing, drawing, image fusion and stereotactic radiotherapy pre-planning) this application provides functions for the import and display of MRI anistropic data, image processing of the DTI data and the display of calculated fiber tracks.

Substantial equivalence:
iPlan RT FiberTracking has been verified and validated according to BrainLAB's procedures for product design and development. The validation proves the safety and effectiveness of the system. The information provided by BrainLAB in this 510(k) application was found to be substantially equivalent with the predicate device iPlan! FiberTracking (K041703) and Intuition Image (K032511).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administrati
9200 Corporate Boulevard
Rockville MD 20850

SEP 30 2005

Mr. Rainer Birkenbach
Executive Vice President
BrainLAB AG
Ammerthalstrasse 8
85551 Heimstetten
Germany

Re: K052220
Trade/Device Name: iPlan RT FiberTracking
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE, MUJ
Dated: August 11, 2005
Received: August 15, 2005

Dear Mr. Birkenbach:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K052220

Device Name: iPlan RT FiberTracking

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format I-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K052220